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| 10/048,185 | 06/17/2002 | Pascual Perez | 34934-PCT-USA 072667.0180 | 2915 |
| 21003 | 7590 | 05/30/2007 | EXAMINER | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/048,185

Applicant(s)

PEREZ ET AL.

Examiner

Keith O. Robinson, Ph.D.

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,23-25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,23-25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action mailed June 25, 2004. Applicant's 'Amendments to the Claims', filed March 13, 2007, have been received and entered in full.
2. Claims 18, 23-25 and 27 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 103

3. Claims 18, 23-25 and 27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida et al (Nature Biotech. 14: 745-750, 1996), in view of Does et al (Plant Mol. Biol. 17: 151-153, 1991), Hiei et al (Plant J. 6(2): 271-282, 1994), Armstrong et al (Theor. Appl. Genet. 84: 755-762, 1992) and Ragot et al (Techniques et utilisations des marqueurs moléculaires, pages 45-56, 1994). The rejection is repeated for the reasons of record as set forth in the previous Office Action mailed December 13, 2006 (see pages 3-5). Applicant's arguments, filed March 13, 2007, have been fully considered but are not persuasive.

Applicant argues that the cited art (Does et al) does not teach or suggest the claim limitation of claim 18, step (b) (see page 7, 1st paragraph to page 8, lines 1-8) of 'Remarks' filed March 13, 2007).

This is not persuasive. Does et al teaches a method of obtaining T-DNA in the genome of plants to amplify plant genomic DNA sequences flanking the known T-DNA sequences by using inverse polymerase chain reaction (IPCR) to amplify plant genomic DNA sequences flanking the known T-DNA sequences and one of ordinary skill in the

art would understand how to modify and use the cited method to select for at least one individual among hybrid primary transformants which have T-DNA integrated only into the genome of the line of interest. In addition, one of ordinary skill in the art would understand how to select for individual plants having T-DNA integrations in their genome. The specification states, "the genomic sequences of the host adjacent to the T-DNA may be isolated and identified, for example via a method based on PCR...preferably IPCR...the aim being to identify the parental origin of the genome which has accepted the transgene" (see page 9, lines 19-25) which uses the method taught by Does et al. So it would be obvious for one of ordinary skill in the art to use Does et al as a method for selecting for individual plants having T-DNA integrations in their genome.

In addition, the Examiner maintains the assertion that the selection performed does not affect the principle component of the claimed step, which is selecting for at least one individual which has T-DNA integrated into the genome of interest because the specification states, "the identification, for each transformant, of the genome of the parental line which has integrated the T-DNA may...be based on demonstrating a polymorphism of the size of the...[RFLP]...between the parental lines and the transformant...[a]lternatively,...demonstrating SNP... by comparison with the sequences of the parental lines may also make it possible to identify the recipient parent genome (see page 9, line 27 to page 10, line 11). The specification teaches that alternative methods may be used to select for at least one individual hybrid primary transformant which has T-DNA integrated into the genome of the line of interest;

therefore, one of ordinary skill in the art would know which techniques to use to make such a selection.

Applicant argues that the Examiner did not identify some suggestion or motivation to combine the cited references and that the proposed combinations would be unsatisfactory for its intended purpose and would change its principle of operation (see page 8, 1st full paragraph to page 9, lines 1-17 of 'Remarks' filed March 13, 2007).

This is not persuasive. In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Ragot et al teach the desirability of isogenic maize lines containing a gene of interest, but otherwise maintaining the genome of an elite agronomic line, including the use of transgenes conferring agronomic properties as the introgressed gene (see page 45, 2nd paragraph; page 46, 3rd full paragraph; page 55, 1st full paragraph). Thus, Ragot et al provides the motivation to produce a method for producing an isotransgenic maize line.

With regards to Applicant's arguments regarding the proposed combinations would be unsatisfactory for its intended purpose and would change its principle of operation, the Examiner maintains that one of ordinary skill in the art would understand how to use the cited teachings to produce the claimed invention. See MPEP 2141.01(a)

where it states, "[i]n order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem."); *Wang Laboratories Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993); and *State Contracting & Eng'g Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1069, 68 USPQ2d 1481, 1490 (Fed. Cir. 2003) (where the general scope of a reference is outside the pertinent field of endeavor, the reference may be considered analogous art if subject matter disclosed therein is relevant to the particular problem with which the inventor is involved).

In the instant case, though Applicant argues that Does et al rely on the ability of a single inserted T-DNA and Hiei et al rely on the use of a super binary vector that is comprised of two different plasmids (see page 9, lines 3-6 of 'Remarks' filed March 13, 2007), one of ordinary skill in the art would recognize that the references are relevant to the particular problem with which the invention is involved and that the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem.

Applicant argues that the Examiner has failed to establish that the proposed combination would have a reasonable expectation of success (see page 9, last paragraph to page 10, end of 2nd paragraph of 'Remarks' filed March 13, 2007).

This is not persuasive. Ragot et al statements (see page 9, last three lines to page 10, three cited sentences" of 'Remarks' filed March 13, 2007) were in reference to the production of isogenic lines through classical backcrossing procedures. Ragot et al, however, used markers to select maize plants carrying a transgene construct where they found "[p]rogress towards recurrent parent genotype was spectacular" (see page 45, Summary). Thus, one of ordinary skill in the art would have reasonable expectation for success because an infinite number of backcrosses would not be required to obtain a truly isotransgenic line.

4. Claims 18, 23-25 and 27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lundquist et al (U.S. Patent No. 5,508,468, April 16, 1996), in view of Chyi et al (Mol. Gen. Genet. 204: 64-69, 1986). The rejection is repeated for the reasons of record as set forth in the previous Office Action mailed December 13, 2006 (see pages 5-7). Applicant's arguments, filed March 13, 2007, have been fully considered but are not persuasive.

Applicant argues that the Examiner appears to be improperly using hindsight to reconstruct the claimed invention using the Applicant's disclosure as a blueprint (see page 11, 1st full paragraph of 'Remarks' filed March 13, 2007).

This is not persuasive. It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long

as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Contrary to Applicant's assertion, the Examiner has not reconstructed the claimed invention using the Applicant's disclosure as a blueprint.

Applicant further argues that Lundquist et al teaches microparticle bombardment which is completely unrelated to the Agrobacterium-mediated introduction of transgenes disclosed in the current claims (see page 11, last sentence to page 12, lines 1-3 of 'Remarks' filed March 13, 2007). However, transformation with Agrobacterium is not a claim limitation and one of ordinary skill in the art would understand that other methods of transformation could be used. See *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem."); *Wang Laboratories Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993); and *State Contracting & Eng'g Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1069, 68 USPQ2d 1481, 1490 (Fed. Cir. 2003) (where the general scope of a reference is outside the pertinent field of endeavor, the reference may be considered analogous art if subject matter disclosed therein is relevant to the particular problem with which the inventor is involved).

Applicant goes on to state that Lundquist et al actually argues against the use of Agrobacterium-mediated methods, pointing that such a system may not even work in maize (see page 12, lines 3-5 of 'Remarks' filed March 13, 2007). However, Lundquist et al do not teach against the use of Agrobacterium-mediated methods. Column 2, lines 5-10, as cited by Applicant, is in reference to a reference by Graves et al which actually reported Agrobacterium-mediated transformation of maize seedlings. Lundquist et al report that the evidence was based upon assays which can **sometimes** be unreliable. Nowhere in does Lundquist et al nor Graves et al argue against the use of Agrobacterium-mediated methods.

Applicant argues that the success or failure of a transformation system in tomato plants (in reference to the Chyi et al reference) is wholly distinct from the currently claimed transformation of maize and that neither Lundquist et al nor Chyi et al provide any motivation to combine their respective teachings to teach or suggest the claimed invention (see page 12, lines 6-13 of 'Remarks' filed March 13, 2007).

This is not persuasive. The Chyi et al reference was used to teach identification of genomic sequences of the host adjacent to the T-DNA and backcrossing individuals to parental lines. The reference was not used to compare the success or failure of a transformation system in tomato plants and maize plants. With regards to Applicant's argument regarding lack of motivation, one of ordinary skill in the art would have been motivated to combine the teachings because Lundquist et al teach "[g]enetic engineering of plants...offers considerable promise to modern agriculture and plant breeding" (see column 1, lines 22-26).

Applicant argues that neither of the cited references teach or suggest the claim limitation of claim 18, step (b) (see page 12, last full paragraph to page 13 of 'Remarks' filed March 13, 2007).

This is not persuasive. As stated in the previous Office Action (see page 6, last paragraph), Chyi et al teach identifying genomic sequences of the host adjacent to the T-DNA and backcrossing individuals to parental lines. One of ordinary skill in the art would understand how to select at least one transgenic individual which has T-DNA integrated only into the genome of the line of interest.

Conclusion

5. No claims are allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is (571) 272-2918. The examiner can normally be reached on 7:30 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson, Ph.D.

May 21, 2007

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

